

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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CIPLA LTD.,

Plaintiff,

v.

SUNOVION PHARMACEUTICALS INC.,

Defendant.  
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Case No. \_\_\_\_\_

**DEMAND FOR JURY TRIAL**

**COMPLAINT FOR PATENT INFRINGEMENT**

For its Complaint against Defendant Sunovion Pharmaceuticals Inc. (“Sunovion”), Plaintiff Cipla Ltd. (“Cipla”), by its undersigned attorneys, allege as to their own acts, and on information and belief as to the acts of others, as follows:

**NATURE OF THE ACTION**

1. This is an action for infringement of United States Reissue Patent No. RE 43,984 (“the RE ’984 Patent”) arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 271, 281, 283-285.

**PARTIES**

2. Cipla Ltd. is a corporation organized under the laws of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Madam Marg, Lower Parel, Mumbai, 400013, India.

3. On information and belief, Sunovion is a corporation organized under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

### **JURISDICTION AND VENUE**

4. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. §§ 271(a), 271(b), 271(c), and 271(e)(2) specifically.

5. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court further has personal jurisdiction because Sunovion is a corporation organized under the laws of the State of Delaware, and therefore, is subject to the laws and protection of the State of Delaware.

7. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b) and (c).

### **THE PATENT-IN-SUIT**

8. On February 5, 2013, the RE '984 Patent, titled "Process for Preparing Isomers of Salbutamol," was duly and legally issued by the United States Patent and Trademark Office. Cipla Ltd. is the owner of all right, title, and interest in the RE '984 Patent. A copy of the RE '984 Patent is attached hereto as Exhibit "A." The RE '984 Patent includes claims that recite levalbuterol tartrate with enantiomeric excess of at least 95% and such levalbuterol tartrate in crystalline form.

### **FACTUAL BACKGROUND**

9. Upon information and belief, Sunovion holds the approved New Drug Application ("NDA") No. 21-730 for Xopenex HFA® Inhalation Aerosol ("Xopenex HFA"), which Sunovion commercially markets in the United States. Xopenex HFA contains levalbuterol tartrate as its active pharmaceutical ingredient. Upon further information and belief, Sunovion's NDA for levalbuterol tartrate was approved by the FDA on March 11, 2005.

10. The prescribing information for Xopenex HFA states that it is a pressurized metered-dose aerosol inhaler, which produces an aerosol for oral inhalation. It contains a suspension of micronized levalbuterol tartrate.

11. Upon information and belief, Xopenex HFA contains levalbuterol tartrate in 95% enantiomeric excess.

12. Upon information and belief, Sunovion engages in the manufacture, importation, use, sale, and/or offer for sale of Xopenex HFA in the United States.

13. Upon information and belief, during the time period relevant to the claims set forth below, Sunovion had knowledge of the RE '984 Patent, including the fact that the RE '984 Patent recited claims to levalbuterol tartrate and, specifically, levalbuterol tartrate with enantiomeric excess of at least 95%.

**SUNOVION'S INFRINGEMENT OF THE RE '984 PATENT**

14. Sunovion's manufacture, importation, use, sale, and/or offer for sale of the levalbuterol tartrate utilized in its Xopenex HFA in the United States infringes one or more claims of the RE '984 Patent.

15. Sunovion's manufacture, importation, use, sale, and/or offer for sale of the levalbuterol tartrate utilized in Xopenex HFA in the United States, upon information and belief, actively and knowingly causes third parties to infringe one or more claims of the RE '984 Patent with the specific intent to cause such infringement.

16. Sunovion's manufacture, importation, use, sale, and/or offer for sale of the levalbuterol tartrate utilized in its Xopenex HFA in the United States is, upon information and belief, intended to contribute to the infringement of the RE '984 Patent by third parties.

17. Sunovion's manufacture, importation, use, sale, and/or offer for sale of the levalbuterol tartrate utilized in its Xopenex HFA in the United States contributes to the infringement of the RE '984 Patent by third parties.

18. As a direct and proximate cause of the infringement, inducement to infringe and contributory infringement by Sunovion, Cipla is being and will continue to be substantially and irreparably harmed in its business and property rights unless Sunovion is enjoined by the Court from manufacturing, importing, offering to sell, selling, or using within the United States products containing levalbuterol tartrate as patented by Cipla.

19. Additionally, Cipla is suffering injury for which it is entitled to monetary relief as a result of Sunovion's infringement, inducement to infringe and contributory infringement.

**COUNT 1**  
**(Sunovion's Infringement of the RE '984 Patent)**

20. Cipla incorporates by reference the allegations contained in Paragraphs 1-19 of the Complaint as if fully set forth herein.

21. On information and belief, the ongoing manufacture, importation, use, sale, and/or offer for sale by Sunovion of Xopenex HFA infringes, either literally or under the doctrine of equivalents, one or more claims of the RE '984 Patent under 35 U.S.C. § 271(a).

22. On information and belief, Sunovion's infringement of the claims of the RE '984 Patent has been and continues to be willful.

**COUNT 2**  
**(Sunovion's Induced Infringement of the RE '984 Patent)**

23. Cipla incorporates by reference the allegations contained in Paragraphs 1-19 of the Complaint as if fully set forth herein.

24. On information and belief, Sunovion had knowledge of the RE '984 Patent.

25. On information and belief, Sunovion actively and knowingly induced another to infringe one or more claims of the RE '984 Patent with the specific intent to encourage such infringement.

26. Sunovion is liable for induced infringement of one or more claims of the RE '984 Patent under 35 U.S.C. §271(b).

**COUNT 3**  
**(Sunovion's Contributory Infringement of the RE '984 Patent)**

27. Cipla incorporates by reference the allegations contained in Paragraphs 1-19 of the Complaint as if fully set forth herein.

28. On information and belief, Sunovion had knowledge of the RE '984 Patent.

29. On information and belief, Sunovion had knowledge that its levalbuterol tartrate active pharmaceutical ingredient can only be used for Xopenex HFA.

30. On information and belief, levalbuterol tartrate is the active pharmaceutical ingredient in Xopenex HFA, and therefore, a material part of Xopenex HFA.

31. On information and belief, Sunovion contributes to the infringement by another of one or more claims of the RE '984 Patent under 35 U.S.C. §271(c).

**PRAYER FOR RELIEF**

WHEREFORE, Cipla respectfully requests that this Court enter a Judgment and Order:

- (a) Declaring that the RE '984 Patent is valid and enforceable;
- (b) Declaring that Sunovion infringes, either literally or under the doctrine of equivalents, at least one valid and enforceable claim of the RE '984 Patent under 35 U.S.C. §271(a);
- (c) Declaring that Sunovion induces the infringement of at least one valid and enforceable claim of the RE '984 Patent under 35 U.S.C. §271(b);

- (d) Declaring that Sunovion contributes to the infringement of at least one valid and enforceable claim of the RE '984 Patent under 35 U.S.C. §271(c).
- (e) Declaring that Sunovion's infringement is willful and Cipla is entitled to treble damages under 35 U.S.C. § 284;
- (f) Awarding Cipla damages adequate to compensate for Sunovion's infringement, but in no event less than a reasonable royalty;
- (g) Preliminarily and permanently enjoining Sunovion, its officers, agents, servants, and employees and those persons in active concert or participation with any of them from manufacturing, importing, offering to sell, selling, or using within the United States products made using and/or containing Cipla's patented product;
- (h) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Cipla its attorneys' fees, costs, and expenses, based in part on, but not limited to, Sunovion's willful infringement; and
- (i) Granting Cipla such other and further relief as this Court deems just, proper, and equitable.

Dated: May 26, 2015

/s/ Mary B. Matterer  
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